health
Department of Health
NORTHERN CAPE

Policy on Conducting Health Research

Version control

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Policy Aim

1. This policy aims to provide a standard framework for support and guidance for conducting health research[1] projects within the Northern Cape Province to respond to the critical health challenges of the Province and ensure that research is conducted in accordance with ethical standards of clinical trials and non-clinical research activities.

Policy Scope

2. This policy applies to all staff of the Northern Cape Department of Health as well as registered students at universities, researchers or stakeholders of the department seeking to undertake health related research involving research participants such as patients, staff of the department, community health workers and/or other resources in the Northern Cape Province.

Policy Statement

3. It is the policy of the Northern Cape Department of Health:

3.1. To provide a framework that applies for all health related researches within the Northern Cape Province involving health staff, patients or resources of the department.

3.2. To establish rational, transparent, and collective decision-making processes around the proposed health related researches within the Province.

3.3. To protect the welfare and rights of research participants through ensuring ethical considerations on all research activities.

3.4. To align the proposed research activities to the Provincial research priority areas.

3.5. To ensure effective communication (internally and externally) about the principles and policies on which the research activities in the Province are founded.

[1] The National Health Act 61 of 2003 defines Health research as any research which contributes to knowledge of the biological, clinical, psychological or social processes on human beings; improved methods for the provision of health services; human pathology; the causes of disease; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and related substances; the development of new applications for health technology

3.6. To co-ordinate, grant, assist and monitor all health research projects by implementing policy on conducting health research and the Standard Operating Procedures.

3.7. To ensure that services are not overburdened by researches and to avoid an overlap.

3.8. To ensure that research findings are made available or disseminated to the appropriate audience and officials for planning and monitoring purposes.

3.9. To efficiently utilise research funds within the province.

3.10. To develop research database that is accessible to researchers and to share information that are public good.

3.11. A research proposal may be denied approval if:

3.11.1. The proposed research is a duplication which burdens health facilities and increases their workload.

3.11.2. Proposed facilities are unable to accommodate the researcher.

3.11.3. There is only partial submission of required documents.

3.11.4. There are issues that may negatively impact in health facilities and patients.

3.11.5. Researchers do not have the appropriate skills to complete the research.

Roles and Responsibilities

4. The roles of the Accounting Officer or his/her delegate is responsible:

4.1. To establishing a Provincial Health Research and Ethics Committee (PHREC) in accordance with the Health Research Policy, 2001, of the National Department of Health.

4.2. To put systems in place for the smooth functioning of the Provincial Health Research and Ethics Committee.

5. The roles of the Research and Development Directorate:

5.1. Provide support including training for provincial research and ethics committee activities.

5.2. Design and develop the standard format which will serve as a guide for approval of research proposals.

5.3. Ensure that all health related research activities within the Northern Cape Province are conducted in full compliance with all applicable legislation, ethical standards, guidelines, regulations and policies.

5.4. Support and collaborate with research stakeholders to increase, manage and structure the external and internal funding for research.

5.5. Chair the PHREC and set the agenda for the committee meeting.

5.6. Engage with respective manager(s) to acquire their permission before approval of research proposals within their sphere of influence.

5.7. Implement decision of actions made by PHREC.

5.8. Create an enabling environment and maintain and enhance the quality of research undertaken within the province.

5.9. Develop research database for information communication and dissemination.

6. The roles of the Provincial Health Research and Ethics Committee (PHREC)

6.1. Support and advise the actions of the Research and Development Directorate in identifying health research priorities within the province.

6.2. Critically review and assess research proposals to be conducted within the province for approval or rejection based on the pre-determined criteria.

6.3. Make recommendations to the Accounting Officer and Member of the Executive Council on research projects that are not adhering to the Research Policy and standards of the Provincial and National Department of Health.

6.4. Liaise with stakeholders, especially with research institutions, to initiate research proposals, mobilise resources for research undertaking, and support in the translation of research findings in policy development and delivery of services in the Province.

6.5. Ensure that research findings are used to inform policy and resource decision making authorities to benefit health service delivery and population health outcomes.

6.6. Conduct the provincial health research priority identification process every three (3) years.

6.7. Review and approve budget and research proposals to be undertaken by staff that involves the Department's resources.

6.8. The following proposals must be submitted to the PHREC:

6.8.1. All health research proposals (clinical and non-clinical) to be conducted within the Northern Cape Province at public health facilities.

6.8.2. All community-based or laboratory-based research proposal that affects the health care workers at public health facilities.

6.8.3. Research proposal that recruits patient or staff from public health facilities as well as community healthcare workers to participate in the study.

6.8.4. Health research proposals that do not fall into the categories 3.11.1 to 3.11.3 and secondary data analysis do not require approval. However, researchers are encouraged to inform and submit their proposals and findings to the Research and Development Directorate.

7. The roles of the Researcher

7.1. Submit proposal with all required documentation[2] to the Research and Development Directorate.

7.2. Have the appropriate skills and ability to complete research.

7.3. Submit final reports to the Research and Development Directorate within three months after completion of the study.

7.4. The approval process is as follows:

7.4.1. Research that will be conducted at a Tertiary institution, specialised hospital and district hospital requires approval from the relevant institution manager.

7.4.2. Clinical trials proposal must be accompanied by an approval letter from the Medicine Control Council and be registered on the National Clinical Trials Register.

7.4.3. Proposals written in other South African official languages must be accompanied by a summary note in English.

7.4.4. Research from foreign (non-South Africans) institutions must acquire approval from the National Department of Health in addition to the PHREC.

7.4.5. Published work must include all acknowledgements of those involved in the project including the relevant government stakeholders.

[2] These include approval letter form the accredited Ethics Committee, consent form, questionnaire and qualifications of the principal researcher

7.4.6. Researchers must submit final reports to the Research and Development Directorate within three months after completion of the study.

Review and Distribution

8. The Director for Research and Development is the responsible manager for this policy and for ensuring it is reviewed and updated.

9. This Policy will be reviewed after 3 years but before 5 years of the last publication date. If necessary an updated version will be issued, if not a formal cover letter will be issued to supplement the cover of this Policy (identifying a revised publication date).

10. The Director for Policy & Planning will distribute updated versions to:

10.1. Member of the Executive Council for Health

10.2. Head of Department of Health

10.3. All Chief Directors, Directors and Deputy Directors (who will in turn distribute to their staff as appropriate.)

10.4. The Chairperson(s) of all Hospital Boards and Clinic/Community Health Centre Committees.

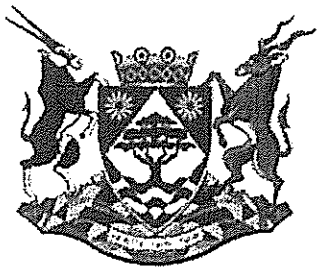
Acknowledgements and Sources

11. Health Research Policy in South Africa, 2001

12. National Health Act 61 (63) Of 2003 as amended.

13. Department of Health. Ethics in Health Research: Principles, Structures, and Processes, 2004 p.59. Department of Health

14. Northern Cape Research and Ethics Committee. Guidelines for Approval of Health Research in the Northern Cape



health

Department of Health
NORTHERN CAPE

PROVINCIAL HEALTH RESEARCH AND ETHICS COMMITTEE (PHREC)

TERMS OF REFERENCE (TOR)

1. Accountability

1.1 All health research conducted in South Africa must be reviewed by a research ethics committee and should not commence until the ethics committee has granted approval. In accordance with the National Health Act, of 2003 and the National Health Research Ethics Council (hereafter referred to as NHREC) the Northern Cape Department of Health (hereafter referred to as NCDOH) established the Provincial Health Research Ethics Committee (hereafter referred to as PHREC).

1.2 The PHREC is guided by the Health Research Policy issued by the National Department of Health (2001).

1.3 The PHREC, before granting approval to a research proposal, must be satisfied that the protocol ensures that the rights and welfare of the research participants is protected.

1.4 Department of Health must accept legal responsibility for the decisions made and advice received from the PHREC.

2. Purpose

The purpose of the Terms of References (TOR) is to determine the mandates, scope of responsibilities, accountability and the standard operating procedures applicable to the PHREC of the Northern Cape Department of Health in accordance with the National Health Act, 2003 (Act No.61 of 2003) and National Health Research Policy of 2001.

3. Scope of Responsibilities and Powers of the PHREC

3.1 Role of the PHREC

The PHREC shall:

3.1.1 Analyze, review, request amendments of research proposals received and approve or reject research proposal;

3.1.2 Monitor, review, and if necessary withdraw approval for any research project that is not conducted in accordance with the ethical standards of clinical trials and non-clinical research activities;

3.1.3 Ensure that human participants involved in research are treated with dignity, their welfare and rights are not compromised and that confidentiality is maintained;

3.1.4 Ensure that informed consent is obtained from human participants;

3.1.5 Provide advice on scientific and technical aspects on the identification and implementation of health research activities conducted in the province and that is in line with the research priorities of the Province and compliant with regulatory requirements;

3.1.6 Ensure that the research findings are used to inform the planning imperatives of the Provincial Department and the improvement of health service delivery.

3.1.7 Ensure that the committee is available to review, advise on, and approve or reject health-related research protocols involving human participants within the borders of the Northern Cape submitted to by researchers from other provinces in the Republic of South Africa or international Researchers;

3.1.8 Consider whether expert advice is required for the accurate consideration of a particular or specific research proposal and activity;

3.1.9 Ensure that, when a project involves more than one institution, the project has obtained ethical approval from each participating institution;

3.1.10 Provide information and reports to the National Health Research Council and National Department of Health.

3.2 The PHERC has the power to:

3.2.1 Take disciplinary steps against researchers who violate either National or the NCDOH's own ethics guidelines.

3.2.2 Take action with regard to Social or health related research which requires participant protection and is conducted by a NCDOH personnel member without prior approval;

3.2.3 Review and refer complaints by members of the Public and any research ethics transgression and/or research-related misconduct brought about by a NCDOH personnel member, to Labour Relations and other appropriate structures.

3.2.4 Deal with adverse and serious adverse events that occur at research sites with minimal delay.

3.2.5 Deal with protocol- deviations and violations with minimal delay.

3.2.6 Conduct monitoring of approved research with or without advance notification given to the Principal Investigator, provided that on arrival at the site the monitor furnishes the researchers on duty with proof of identification and mandate from the PHREC.

4. Code of Ethics

4.1 The overarching ethics guidance for NCDOH will be the (2004) National Department of Health Ethics in Health Research: Principles, Structures and Processes. For clinical trials, The National Department of Health (2006) South African Good Clinical Practice Guidelines will apply. Where relevant, the SA MRC Guidelines and major international guidance documents such as the CIOMS guideline, the most recent version of the Declaration of Helsinki and UNSECO guidelines might apply.

4.2 The NCDOH and its employees commit themselves to a Code of Values that are consistent with the goal and vision of the NCDOH as captured in the NCDOH Annual Performance Plan of 2012/13-2014/15. The values that guide NCDOH include: Respect; Integrity; Excellence through effectiveness, efficiency, innovation and quality health care; humanity and to empower its people.

5. Governing Principles

The PHREC adheres to the following broad principles:

5.1 Standardized and transparent procedures

5.2 Holding of regular meetings and minutes of all meetings should be captured

5.3 Avoidance of conflicts of interest by members

5.4 Provision of an appeal procedure

5.5 Regular reporting to the NCDOH Head of Department (hereafter referred to as HOD)

6. Composition and Membership of the PHREC

6.1 The Provincial Health Research Ethics Committee should consist of members who, collectively, have various levels of skill expertise and knowledge to review and evaluate different types of research protocols;

6.2 The Provincial Health Research Ethics Committee is composed of thirteen (13) members;

6.3 Members, including community members are appointed and ratified by the HOD in consultation with the Research and Development Directorate. A PHREC must have:

6.3.1 A Chairperson;

6.3.2. At least one external member who is nominated by the institution they serve;

6.3.3 At least two community members who have no affiliation to the Department;

6.3.4 At least one member with knowledge of, and current experience in, areas of research that is likely to be regularly considered by the ethics committee;

6.3.5 At least two people with current research experience that is relevant to health research;

6.3.6 Internal members are selected based on the level of expertise, seniority in the department as well as experience in the health, social and research field;

6.3.7 The Committee endeavors to achieve gender and racial proportions among the members as required by the Health Act related guidance for accredited PHRECs;

6.4 The committee with the approval of the Chairperson, may solicit external individuals or NCDOH staff with specialized knowledge if the expertise of the standing committee is considered to be lacking in that specific field of expertise.

6.5 The period of the appointment for PHREC to serve in a committee is two (2) year term of office subjected to annual confirmation, and may make themselves available for further two-year period;

6.6 Members shall be given a formal notice of appointment.

6.7 Members have the assurance that the NCDOH shall provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as Committee Members;

7. Chairpersonship

7.1 Appointment

7.1.1 The Chairperson of the Provincial Health Research Ethics Committee will be the Director of the Research and Development Directorate and appointed by the Accounting Officer.

7.2 **Powers of the Chairperson**

The Chairperson

7.2.1 Takes responsibility and accountability for the final approval of research proposals that do not involve clinical trials;

7.2.2 May solicit expert resources for specific research activities;

7.2.3 May co-opt any member with the aim of performing certain duties of the NCPHREC;

7.2.4 May appoint additional member to the NCPHREC, if required, based on the approval of the Head of Department;

7.2.5 Represents the NCPHREC in meetings with National Health Research Committee;

7.2.6 May delegate all these powers to a nominated person.

8. Recording of Decisions

8.1 The PHREC shall maintain a record of all research protocols received and reviewed .

9. Monitoring

9.1 The PHREC has the responsibility to monitor and ensure that research is conducted appropriately;

9.2 The PHREC may require a researcher to inform the committee on the progress of the research.

10. Appeals

10.1 In a case where a researcher wishes to contest a decision made by the PHREC, he/she will appeal to the HOD. In such case, the HOD may refer the case to another organization's accredited Research Ethics Committee for a second opinion before providing his/her ruling.

11. Remuneration

11.1 The community members of the PHREC will be remunerated in accordance with the NCDOH approved policies, and in line with Treasury and related prescripts;

All necessary and essential expenses incurred by members in carrying out the duties in line with the ethical research approval will be reimbursed.

12. Standard Operating Procedures (SOPs)

12.1 Meeting

12.1.1 Six meetings will be held each year. The PHREC will meet every second month (except in December and January) with a quorum for a meeting to take place shall be seven (7) members including the chairperson;

12.1.2 The Chairperson may reschedule or convene meetings on ad hoc basis if required;

12.1.3 Agenda and minutes of previous meeting will be prepared by the Chairperson and secretariat and will be distributed to the Committee members at least two weeks before the meeting;

12.1.4 Committee members will receive formal invitation to committee meetings at least two weeks before the meeting;

12.1.5 Committee members will be required to confirm their availability within 3 days after written notification received;

12.2. Administrative support

12.2.1 The Provincial Research and Development Directorate will provide secretariat services to the PHREC;

12.2.2 An administrative official will be assigned to support the work of the PHREC. **The official shall;**

12.2.2.1. Receive research proposal applications and assign PHREC numbers to protocols;

12.2.2.2. Check that the research proposal application is completed and signed by the Principal Investigator;

12.2.2.3 Compile and distribute papers, including applications and supporting documents, one week prior to the meeting;

12.2.2.4 Prepare agenda and minutes of the discussions and evaluation of applications as well as disseminate to all members of the PHREC within two weeks prior to the meeting;

12.2.2.5 Provide written notification of decisions to applicants within two weeks of each PHREC meeting;

12.2.2.6 Issue invitations to members to attend meetings two weeks prior to the meeting;

12.2.2.7 Maintain register for requested/proposed and approved research proposals;

12.3 Researchers

12.3.1 Researchers must submit written applications for ethics clearance and/or approval to conduct research in the province on a prescribed form. The file shall include

13.1.1 The research protocol,

13.1.2 Information sheets,

13.1.3 Informed consent forms,

13.1.4. Questionnaires

13.1.4 Relevant correspondence related to the proposal

12.3.2. Researchers should provide progress and final research reports to the PHREC and other stakeholders;

12.4 Proposal Review

12.4.1 The committee, after considering inputs from the committee members on a submitted proposal, would make one of three decisions by consensus: approval; require amendments or rejection;

12.4.2 Proposals requiring amendments are to be re-submitted to the committee. Rejected submissions may be re-submitted for fresh review by the committee;

12.4.3 Committee members whose applications are being discussed must declare their interest in such applications and excuse themselves for that part of a meeting or by the request of the committee may remain present to provide points of clarification. They are, however, not part of the decision making process;

12.4.4 A senior manager of NCDOH may be invited to attend a meeting to guide the committee on the benefits of the proposed research to NCDOH. They are,however, not part of the decision making process.

12.4.5 If there is an urgent need for approval of a proposal, a submission for expedited approval may be made through PHREC secretariat, Chairperson or Deputy Chairperson (the Executive members).

12.4.6. If the Executive members are satisfied that the circumstances justify urgent review, they may:

12.4.6.1. Decide that an approval may be given

12.4.6.2 Refer the application for any other member or members of the PHREC for comment to assist the Executive in deciding whether or not the approval should be given.

12.4.6.3 Require amendment of the approval

12.4.6.4. Refuse to give executive approval.

12.4.7 An executive approval does not require further approval but all executive approval must be submitted to the next meeting of the PHREC for noting.

12.5 Recording of Decisions

The PHREC shall maintain a record of all research protocols received and reviewed including:

12.5.1 Name of responsible institution or organisation;

12.5.2. Project identification number;

12.5.3. Principal investigator;

12.5.4. Title of the project;

12.5.5 Date of ethical approval or non-approval;

12.5.6 Complaints from researchers whose protocols were not approved;

12.6 Monitoring of Approved Research Projects

12.6.1 A research ethics committee must request at regular periods, at least annually, reports from the principal investigator to monitor compliance with the research protocol;These including:

- Progress to date, or outcome in the case of completed research;
- Information concerning maintenance and security of records;
- Evidence of compliance with the approved protocol;
- Evidence of compliance with any conditions of approval;

12.6.1 Research ethics committees should inform the principal investigator, in writing, of decisions made after the review of progress reports;

12.6.3. PHREC may oversee and make site visits to monitor progress of research activities. Monitoring may include the random inspection of research sites, data and signed consent forms.

12. 7 Complaints

12.7.1 Any researcher who has complaints has the right to forward a complaint to the PHREC and get response within a month;

12.7.2 If the response of the PHREC is not adequate the researcher has the right lodge the complaint with the National Research Ethics Council

12.8 Suspension or Discontinuation of Research

12.8.1 Where a research ethics committee is satisfied that such circumstances have arisen that a research project is not being conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the research ethics committee may withdraw approval;

12.8.2 The research ethics committee shall also inform the researcher and the institution or organization of its action, and shall recommend that the research project be discontinued or suspended, or those other appropriate steps be taken;

12.8.3 Where ethical approval has been withdrawn, a researcher must discontinue the research and comply with any special conditions required by the ethics committee.

13. Training

13.1 All committee members must receive initial and ongoing training in research ethics and committee work.

14. Scientific Integrity and Guidelines for Research Proposals

The proposed research must demonstrate sound methodology and a high probability of providing answers to the research questions posed. The research proposal should include the following:

14.1 **Title:** a concise statement of the main topic and should reflect the contents of the document.

14.2. **Principal investigator's name and affiliation**

14.3 **Introduction:** this section should provide the summary of the proposal

14.4 **Background:** should highlight the problem, talk about the target group in the study.

14.5 **Statement of the problem:** must give information what the problem is, why and how it is a problem.

14.6 **Objectives and research questions:** one general objective which should be in line with the title and specific objectives which are in line with the variables the researcher hypothesize to influence the phenomenon being investigated. Questions should be related to the general objective and they should be in line with the specific objectives

14.7 Methods:

14.7.1 Study design: Study design should specify whether the study is descriptive, analytical or an intervention.

14.7.2 Study population: The study population should be clearly stated in terms of gender age, geographical location and any related relevant information.

14.7.3. Sampling: The sampling frame should include techniques used in sampling participants as well as the sample size.

14.7.4. Inclusion and exclusion criteria: The criteria used should be clearly stated.

14.7.5. Data collection: Instruments used for data collection should be specified and included with the research proposal submitted to the Provincial Health Research Committee.

14.7.6. Data analysis: Data analysis techniques that will be used when the research project is completed.

14.7.7. Pilot study: The research proposal should outline the undertaking of a pilot study to evaluate the data collection instruments before the main study.

14.8 Ethical considerations: this section indicates what ethical issues were considered during the development of the research proposal including the Informed Consent issues and should illustrate why the researcher is conducting the research and whom it shall benefit.

14.9 Limitation: not a must for a proposal, but if there if there is a potential challenge that may have limited the study.

14.10 Feedback and dissemination of research findings: This section clearly outlines a strategy for feedback and dissemination of information to relevant stakeholders. It includes reports, presentations and publications. It is important to note that reports, presentations and publications should formally acknowledge the Provincial Department.

14.11 Budget: The research budget should be clearly outlined. Application for funding for research projects will have to be arranged with funding institutions by the Researcher. The Department has no funding allocation for research projects.

14.12. **Time Frame:** Researchers have to provide a realistic time frame for research projects.

14.13 **Expected outcomes of the research:** In this section the researcher states what he or she expects to achieve from the research activity that will contribute towards public health knowledge.

14.14. **References and appendices**: Literature used during the development of a research proposal should be properly referenced. Relevant appendices should be inserted at the end of the research proposal and should include the data collection instruments or tools and any relevant documentation referred to in the research proposal.